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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/729,199

12/05/2003

Jan Lewandowski

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

06/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/729,199 | | LEWANDOWSKI ET AL. | |
| | Examiner | | Art Unit | |
| | Jaworski Francis J. | | 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 12 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/5/3;7/2,8/2,12/9/4;1/7,8/26/5;3/8/7.

DETAILED ACTION

Applicants' intent to file an interference has been noted, however 37 C.F.R. 41.102 requires that 1) examination must be completed in both cases prior to declaration of an interference. Otherwise, 2) both applications must of course be active at that time when a declaration of interference would now be proper.

[All of claims 1 – 13 as presented in the preliminary amendment filed May 9, 2005 are under examination.]

Disclosure Objections/Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The disclosure is objected to because of the following informalities:

The preliminary amendment filed May 9, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The subject matter of claims 9 – 11 is unsupported by the original disclosure, which provides a reference basis for viscosity based on a stomach mucin analog and uses binary regression modeling to mathematically relate measured amplitudes to

viscosity for a given patient and does not involve ranges derived from a population base or normalization concepts.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 9 - 11 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for features described above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1- 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Teele (US4601295), or in the alternative as obvious based on Teele et al in view of Wong et al (US4691714).

The former is directed to an apparatus and method for detecting middle effusion of fluid (col. 3 lines 11 – 12 and col. 5 bottom portion) which includes a sound field transducer 21 (however 'transducer' is understood to overlap into the supra-audible i.e. ultrasound range e.g. 10.5, 14 Khz) , and

a swept frequency versus amplitude analysis device such that spectral tracings of normal and middle ears may be produced per Fig. 4.

Under an anticipatory interpretation this analysis suffices as a viscosity determination since that specification makes clear that fluid presence is responsible for the mechanical impedance changes that produce the individualized curve.

In the alternative, since the terms viscosity or viscous are not literally mentioned in Teele et al, it would have been obvious in view of Wong et al (which is directed to a surface wave viscosimeter of body fluid) to associate mechanical impedance amplitude changes with degree of viscosity, hence while eardrum pressure or tautness would

contribute a dominant effect to the Teele et al trace, the viscosity of the fluid behind the ear would necessarily contribute to the measured output trace.

[Effectively the examiner is arguing here that Teele in and of itself is a viscosimeter because its result in the sense of fluid/no fluid present is in part predicated on the difference in viscosity between fluid generically or air, and that Teele et al in view of Wong et al proposes that at least some characteristics of the Teele et al trace would be influenced by the degree of viscosity (serous or mucus for example) in the material behind the tympanic membrane. This dual reasoning pertains to both the apparatus and method claim set since Teele et al's is directed to the same purpose and reason as the applicants' method.]

Claims 12 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teele et al alone or further in view of Wong et al.

The above argument that the effusion free/effusion present thresholding in Teele is a form of viscosity measurement or an at least qualitative relationship of mechanical impedance change with degree of viscosity would have been further obvious in view of Wong et al is continued with respect to this method claim set, however since antibiotic treatment is not mentioned it would have been inherently obvious to a physician entertain such for treating otitis media in children.

Claims 1 – 6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Alford (Jrnl Amer. Academy of Audiology V1 No.4 (1990), of record) insofar as Alford Figs. 6 and 10 are respectively representative of A-scan and B-scan images in which middle ear effusions insofar as

they present as image patterns discernible with respect to the normal case serve as rudimentary viscosimeter displays which distinguish air versus fluid presence.

In the alternative, since viscosimetry is not literally mentioned, the argument is made that since the respective A-scan reflectance amplitude and B-mode display intensity are based on the mechanical impedance of the intervening medium, these displays as pertain to normal middle ear versus effusion would necessarily be affected by viscosity change on the order of air-filled versus fluid filled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 – 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hormann (Abstr. Acta Otolaryngol. Suppl. 1987;440:1 – 59) and Teele et al. The former teaches that the pathogenic course of middle ear infusions in an animal analog designed to track child patient management is characterizable by a severality of middle ear effusion viscosity ranges and that impedance tympanometry may be used to track these viscosimetry ranges, the latter being represented by Teele et al further presents that impedance tympanometry can distinguish between the different pathogenic forms of otitis when used in such a context. The use of fixed values to define ranges would have been well-known since this merely provides quantification as to what is meant by low, high, extremely high viscosities.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 8 above, and further in view of Brainard et al (US6048320, of record with the 3/8/07 IDS). Since Brainard et al notes in col. 5 that impedance has to be referenced to patient age in order to discern substantive variations, it would have been obvious in applying the Hormann model to a pediatric population to use patient age in comparison to a population reference in order to make sense of measured impedance values.

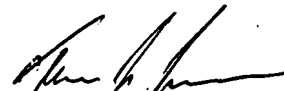
Allowable Subject Matter

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

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Francis J. Jaworski
Primary Examiner